K010635

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SUMMARY OF SAFETY AND EFFECTIVENESS

Applicant/Sponsor:	Biomet, Inc. 56 East Bell Drive Warsaw, Indiana 46582
Contact Person:	Mary L. Verstynen Telephone: (219) 267-6639 Fax: (219) 372-1683
Proprietary Name:	Interlok®/HA Copeland™ Resurfacing Heads
Common Name:	Humeral head resurfacing component
Classification Name:	prosthesis, shoulder, hemi-, humeral, metallic, uncemented Class II

Legally Marketed Devices To Which Substantial Equivalence Is Claimed:
Copeland™ Resurfacing Heads: K003044, Bio-Modular Shoulder System: K992119

Device Description: These devices are humeral heads with spherical articulation geometry containing a tapered, fluted stem for fixation. The devices have an Interlok® with hydroxyapatite (HA) surface finish to the stem and inside spherical radius.

The humeral head components are available in four sizes (x-large, large, standard, and small). The radius of curvature is identical for the small, standard and large sizes, but the heights differ to cater for the range of anatomical sizes and offsets. The x-large size has an increased radius of curvature to coincide with the anatomy. The stem is tapered and fluted to provide maximum stability in the humerus. The components are manufactured from cobalt-chrome-molybdenum alloy (ASTM F-75) with the Interlok®/HA non-articulating surface.

These devices are intended for uncemented use and are designed to maintain maximum bone stock by removing minimal bone and replacing only the defective surface. Copeland™ Resurfacing Heads can be used in hemi- or total shoulder replacement surgical procedures. By preserving the bone stock, these devices give patients an alternative to other total shoulder devices where more bone is removed.

Intended Use: The Interlok®/HA Copeland™ Resurfacing Heads are indicated for the following conditions where the humeral head and neck are of sufficient bone stock and there is presence of an intact or reconstructable rotator cuff which is necessary for proper functioning and dislocation resistance:

1) Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis.
2) Rheumatoid arthritis

3) Correction of functional deformity
4) Reconstructable rotator cuff
5) Treatment of fractures of the humeral head
6) Traumatic arthritis

For uncemented use only.

Summary of Technologies: The Interlok®/HA Copeland™ Resurfacing Heads have the same design as the predicate Copeland™ Resurfacing Heads. The predicate devices are porous coated devices cleared for cemented use, whereas, this submission contains devices with an interlok®/HA coating for uncemented use. Clinical data was supplied to address these differences.

Non-Clinical Testing: Non-applicable

Clinical Testing: Sixty-nine Interlok®/HA Copeland™ Resurfacing Heads were implanted in cementless surface replacement athroplasty of the shoulder starting in 1994. The minimum follow-up was 24 months with no revisions reported. Radiographically, no lucencies were observed surrounding these implants. These clinical results provide adequate data to demonstrate the substantial equivalence of the Interlok®/HA Copeland™ Resurfacing Heads.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 0 2001

Ms. Mary L. Verstynen
Manager of Clinical Affairs
Biomet, Inc.
P.O. Box 587
Warsaw, Indiana 46581-0587

Re: K010635
Trade/Device Name: Interlok®/HA Copeland™ Resurfacing Heads
Regulation Number: 888.3670, 888.3690
Regulatory Class: II
Product Code: MBF, HSD
Dated: May 25, 2001
Received: May 29, 2001

Dear Ms. Verstynen:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510 (k) Number (if known) : K010635

Device Name: Interlok®/HA Copeland™ Resurfacing Heads

Indications For Use:

The Interlok®/HA Copeland™ Resurfacing Heads are indicated for the following conditions where the humeral head and neck are of sufficient bone stock and there is presence of an intact or reconstructable rotator cuff, which is necessary for proper functioning and dislocation resistance:

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(PLEASE DO NOT WRITE BELOW THIS LINE. CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

OR Over-The-Counter-Use_____
(Optional Format 1-2-96)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K010635

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